DMB

Display Date 1-26-00
Publication Date 1-27-00
Certifier M. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99E-0119]

Determination of Regulatory Review Period for Purposes of Patent Extension; Sentinel Model 2000/2010®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Sentinel Model 2000/2010® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Claudia V. Grillo,
Regulatory Policy Staff (HFD-007),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-594-5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Sentinel Model 2000/2010®. Sentinel Model 2000/2010® is indicated for use in patients with documented ventricular fibrillation and/or ventricular tachycardia, or in patients who are at high risk of sudden cardiac death. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Sentinel Model 2000/2010® (U.S. Patent No. 5,405,363) from Angieon Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 9, 1999, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Sentinel Model 2000/2010® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Sentinel Model 2000/2010® is 1,030 days. Of this time, 603 days occurred during the testing phase of the regulatory review period, while 427 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: October 26, 1995. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21

U.S.C. 360j(g)) for human tests to begin became effective on September 28, 1995. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on October 26, 1995, which represents the IDE effective date.

2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): June 19, 1997. FDA has verified the applicant's claim that the premarket approval application (PMA) for Sentinel Model 2000/2010® (PMA P970024) was initially submitted June 19, 1997.

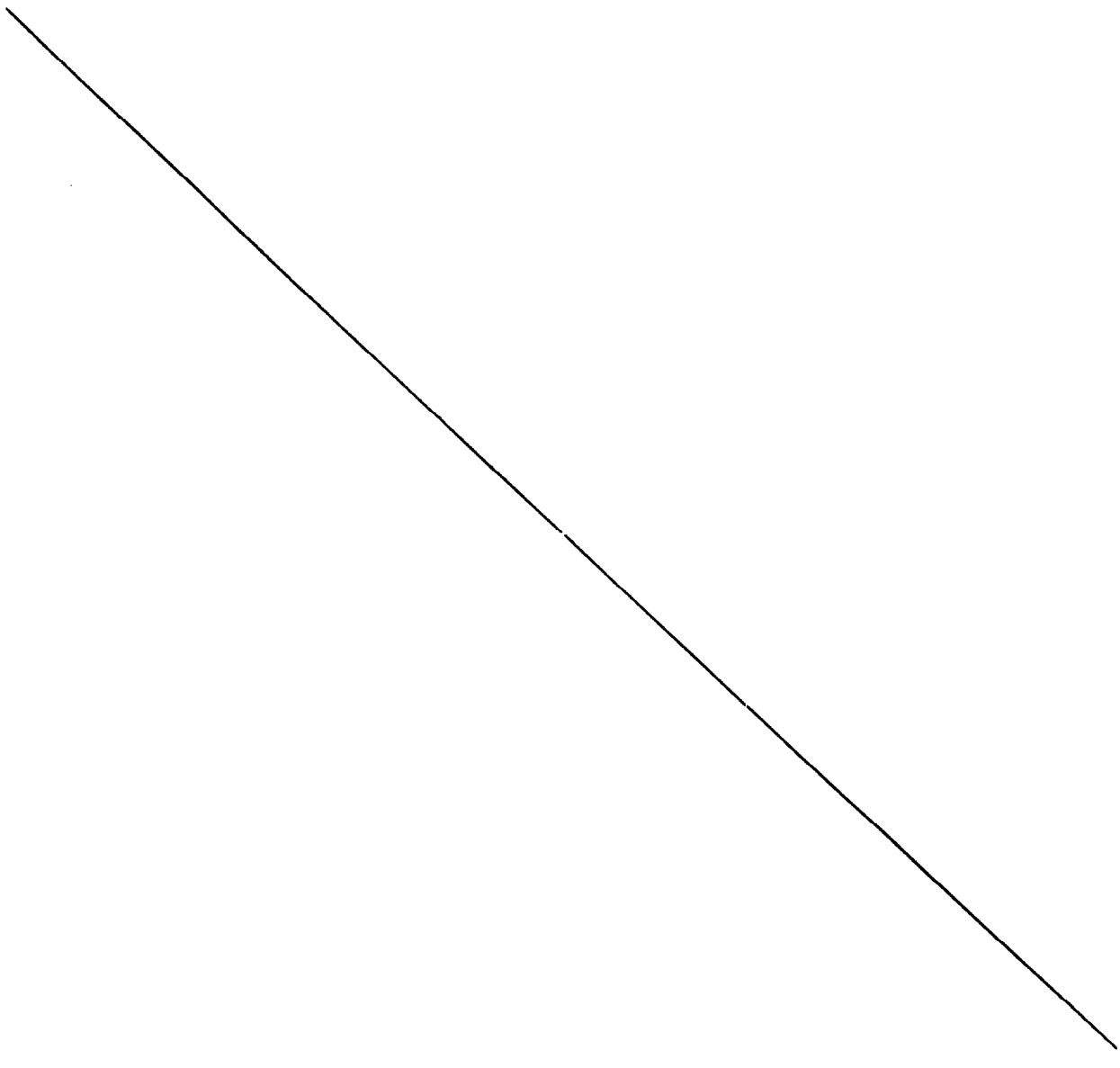
3. The date the application was approved: August 19, 1998. FDA has verified the applicant's claim that PMA P970024 was approved on August 19, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 132 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before [insert date 60 days after date of publication in the FEDERAL REGISTER], submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before [insert date 180 days after date of publication in the FEDERAL REGISTER], for a determination regarding whether

the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the



docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 23, 1999.
December 23, 1999

Jane A. Axelrad

Jane A. Axelrad

Associate Director for Policy
Center for Drug Evaluation and Research

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Michael W. Bell